MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

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Decision Cover Letter

Decision of the licensing authority to:

accept of change(s) to the agreed paediatric investigation plan and to the deferral.

MHRA-101879-PIP01-25-M01

Scope of the Application

Active Substance(s)

BECLOMETASONE DIPROPIONATE; FORMOTEROL FUMARATE DIHYDRATE; GLYCOPYRRONIUM BROMIDE

Condition(s)

Treatment of Asthma

Pharmaceutical Form(s)

Pressurised inhalation, solution, Inhalation powder

Route(s) of Administration

INHALATION USE

Name / Corporate name of the PIP applicant

Chiesi Ltd

Basis for the Decision

Pursuant to the Human Medicines Regulations 2012, Chiesi Ltd submitted to the licensing authority on 31/03/2025 13:04 BST an application for a Modification

The procedure started on 08/07/2025 08:54 BST

1. The licensing authority, having assessed the application in accordance with the Human Medicines Regulations 2012, decides, as set out in the appended summary report:

to accept change(s) to the agreed paediatric investigation plan and to the deferral.

2. The measures and timelines of the paediatric investigation plan are set out in the Annex I.

This decision is forwarded to the applicant, together with its annex and appendix.

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Final Decision Letter

MHRA-101879-PIP01-25-M01

Of 21/08/2025 09:36 BST

On the adopted decision for BECLOMETASONE DIPROPIONATE; FORMOTEROL FUMARATE DIHYDRATE; GLYCOPYRRONIUM BROMIDE (MHRA-101879-PIP01-25-M01) in accordance with the Human Medicines Regulations 2012.

The licensing authority, in accordance with the Human Medicines Regulations 2012, has adopted this decision:

Agreement on modification of a paediatric investigation plan (including modification of a waiver or deferral included in that paediatric investigation plan).

This decision applies to a Modification for BECLOMETASONE DIPROPIONATE; FORMOTEROL FUMARATE DIHYDRATE; GLYCOPYRRONIUM BROMIDE, Pressurised inhalation, solution, Inhalation powder , INHALATION USE .

This decision is addressed to Chiesi Ltd , 333 Styal Road, Manchester, UNITED KINGDOM, M22 5LG

ANNEX I

1. Waiver

1.1 Condition:

Treatment of asthma The waiver applies / applied to: Paediatric Subset(s): The paediatric population from birth to less than 5 years of age For the Pharmaceutical form(s): Pressurised inhalation, solution And Paediatric Subset(s): The paediatric population from birth to less than 18 years of age For the Pharmaceutical form(s): Inhalation powder Route(s) of administration: Inhalation use Reason for granting waiver: on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan:

2.1 Condition(s):

Treatment of asthma

2.2 Indication(s) targeted by the PIP:

Treatment of asthma in patients not controlled with medium-high doses of inhaled corticosteroids and long-acting beta2-agonists.

2.3 Subset(s) of the paediatric population concerned by the paediatric development:

The paediatric population from 5 years to less than 18 years of age.

2.4 Pharmaceutical Form(s):

Pressurised inhalation, solution

2.5 Studies:

Study Type	Number of Studies	Study Description
Quality Measures	0	Not applicable.
Non-Clinical Studies	0	Not applicable.
Clinical Studies	4	Study 1 (CLI-05993CB1-01) Open label, non-randomised single dose pharmacokinetic (PK)/ pharmacodynamic (PD) study of beclometasone dipropionate, formoterol fumarate and glycopyrronium bromide (CHF 5993) in adolescent asthmatic patients 12 years to less than 18 years of age (and adult and asthmatic patients). Study 2 (CLI-05993AA5-06) Double blind, parallel group, study to assess safety and efficacy of CHF 5993 versus fluticasone propionate / salmeterol xinafoate (FP / SLM) pMDI (Seretide 125 Evohaler) as comparator in adolescents from 12 years to less than 18 years of age with uncontrolled asthma Study 3 Double-blind randomised, crossover, active-controlled study to evaluate pharmacokinetics (PK) efficacy, safety and tolerability of CHF 5993 and children from 5 years to less than 12 years of age with uncontrolled

		asthma. Study 4 Double-blind, randomised, parallel group active controlled study to evaluate the efficacy in safety or CHF 5993 in children from 5 years to less than 12 years of age with uncontrolled asthma.
Extrapolation, Modeling & Simulation Studies	0	Not applicable.
Other Studies	0	Not applicable.
Other Measures	0	Not applicable.

3. Follow-up, completion and deferral of a PIP:

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	30/09/2033
Deferral of one or more studies contained in the paediatric investigation plan:	Yes